

The opinion in support of the decision being entered today was *not* written for publication and is *not* binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JIN PO LEE

Appeal 2006-1846
Application 10/019,570
Technology Center 1700

Decided: September 29, 2006

Before WARREN, KRATZ, and GAUDETTE, *Administrative Patent Judges*.

GAUDETTE, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the decision of the Examiner finally rejecting claims 10-17, and 19. Claims 8 and 20-25 have been withdrawn. Claims 1-7, 9, and 18 are also pending and finally rejected, but are not appealed. Accordingly, we dismiss the Appeal with respect to claims 1-7, 9 and 18.

Claim 10 is representative of the claims on appeal:

10. A device for assaying a fluid for the presence or absence of different analytes comprising:

(A) a base having adjacent slots thereto of sufficient length for insertion of a test strip therein, wherein each slot is defined by (a) a floor, (b) raised walls depending upwardly from the floor to separate each adjacent slot from the next, and (c) at least one open end;

(B) a multiplicity of test strips having an upstream and a downstream end, wherein a single test strip is inserted into each slot of the base so the upstream end of each test strip protrudes out of the open end of each slot, and wherein each test strip has a test zone and a control zone therein, and each test zone contains a binder specific for a different analyte;

(C) a cover having (a) a first section attached to the upwardmost surface of each raised wall of the slots of the base, wherein the first section of the cover retains the test strips within the slots and has a first transparent window formed therein through which the test zone and the control zone of each of the test strips can be viewed and (b) a second section enclosing the protruding ends of the test strips, the second section comprising:

(i) a sample port formed through which fluid analyte sample may be applied to the protruding ends of the test strips;

(ii) a floor opposing the sample port, the floor comprising a wall having a raised bar therein which defines a fluid reservoir beneath the sample port.

The reference relied on by the Examiner is:

Klimov US 5,770,458 Jun. 6, 1998

The Examiner has advanced the following grounds of rejection on appeal:

Claims 10-17, and 19 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent 6,514,769.

Claims 10-17, and 19 under 35 U.S.C. § 102(e) as anticipated by Klimov.

We affirm.

We refer to the Answer and to the Brief (Revised) and Reply Brief for a complete exposition of the positions advanced by the Examiner and Appellant.

OPINION

The invention relates to a multiple analyte assay device which is said to prevent cross contamination of the assay strips contained in the housing and any exposure of the operator to the sample. (Br. 3, ll. 26-28).

Appellant does not present separate arguments with respect to any particular claim. Therefore, we decide this appeal based on appealed claim 10 as representative of the grounds of rejection

Claims 10-17, and 19 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of US 6,514,769. The Examiner maintains that the present claims are not patentably distinct from those of the '769 patent because both are directed to a test device having a base with adjacent slots for separating the test strips. (Answer 4).

During prosecution, Appellant traversed this ground of rejection, but later filed a Terminal Disclaimer responsive to the Final Rejection in order to advance prosecution. The disclaimer was approved by the Examiner prior to the filing of the Appeal Brief. *See* Advisory Action mailed March 29, 2005. The rejection was, however, reasserted in the Examiner's Answer after it was discovered that Appellant had made a typographical error in

referencing the application being disclaimed. (*See* Answer 2-3). In his Reply Brief, Appellant traverses the double-patenting rejection.

The Examiner found that “sample integrity monitoring system” as recited in the ‘769 patent claims reads on the presently claimed control zones. (Final Rejection 4). Claim 1 of the ‘769 patent recites:

A device for use in determining whether the integrity of a fluid analyte sample has been compromised and for contemporaneously assaying the sample for the presence or absence of multiple analytes, the device comprising:

(A) a base having adjacent slots therein of sufficient length for insertion of an analyte test strip therein, wherein each slot is defined by (a) a floor, (b) raised walls depending upwardly from the floor to separate each adjacent slot from the next, and (c) at least one open end

(B) a multiplicity of analyte test strips having an upstream and a downstream end, wherein each analyte test strip occupies a separate slot of the base so the upstream end of each analyte test strip protrudes out of the open end of each slot for application of the fluid analyte sample;

(C) a sample integrity monitoring system, the system comprising: (a) a carrier membrane which lies parallel with and underlies each analyte test strip; (b) a sample integrity determinant pad in fluid communication with the carrier membrane; and, (c) determinants incorporated into the integrity determinant pad, which determinants provide a detectable signal for a parameter indicative of the condition of the fluid.

Claims are unpatentable under the doctrine of nonstatutory obviousness-type double patenting if the application claims merely define an obvious variation of the relied upon patent claims. *In re Berg*, 140 F.3d 1428, 1432, 46 U.S.P.Q.2d 1226, 1229 (Fed. Cir. 1998). Appellant argues

the present claims are patentably distinct from those of the '769 patent in that the present claims do not recite a sample integrity monitoring system involving a separate second assay strip for each analyte tested. However, Appellant has not has not explained why the presently claimed test strips, having both a test and a control zone, would not have been an obvious variant of the analyte test strips and underlying carrier membrane of the '769 patent claims. Appellant further argues that the present claims are patentably distinct because the claims of the '769 patent do not include the limitation of a removable cap on the exposed assay strips which allows the device to be used as a cassette. (Reply Br. 4). Again, Appellant fails to explain why the cover, as claimed, would not have been an obvious variant of claim 2 of the '769 patent which includes the limitation of a cap for insertion over the protruding ends of the analyte test strips and of claim 11 which includes the limitation that "the device includes a cover overlying the slots of the base and each test zone of the analyte test strips is visible through a transparent window through the cover."

Accordingly, the rejection of claims 10-17 and 19 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent 6,514,769 is affirmed. Should Appellant elect to continue prosecution of the application, this rejection may be overcome by the filing of a new Terminal Disclaimer.

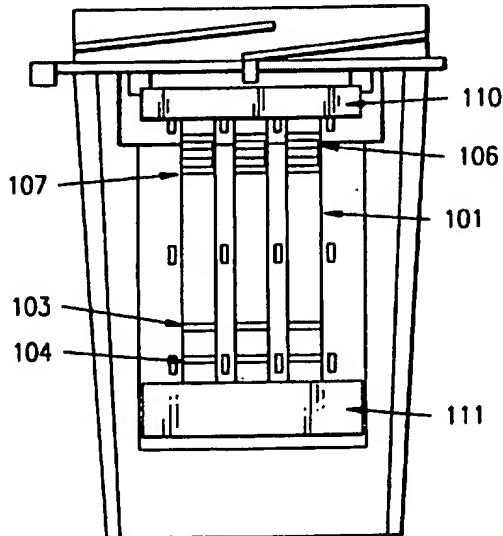
Claims 10-17 and 19 are rejected under 35 U.S.C. § 102(e) as anticipated by Klimov. Appellant argues that Klimov does not anticipate the claims because Klimov fails to disclose the following features:

- (1) slots in a housing for the assay strips with walls between the slots,
- (2) strips extending beyond the housing, and
- (3) a cover for the extended strips which provides a sample port and reservoir for sample analysis. (Br. 4, l. 32 – 5, l. 3).

The Examiner's position with respect to each of the above claim limitations as follows:

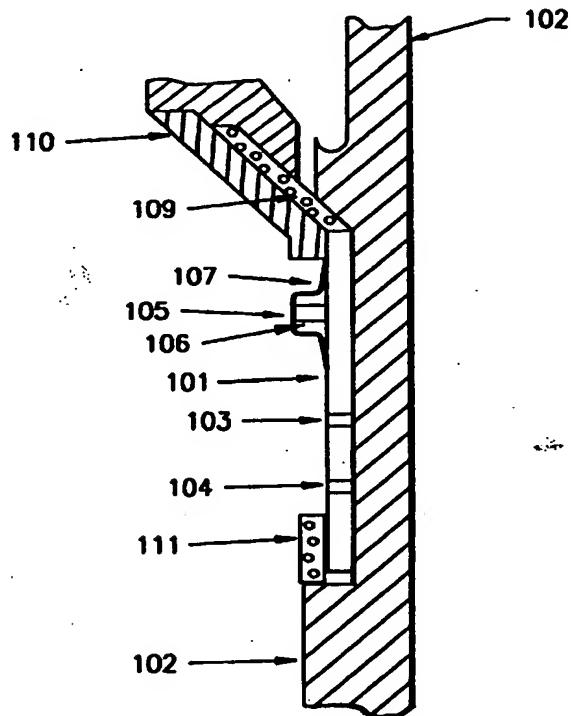
(1) slots in a housing for the assay strips with walls between the slots

The Examiner relies on Klimov for a teaching of a plastic holder 102 having a plurality of slots for receiving test membranes 101. (Answer 4). According to the Examiner, Figures 1A-1B of Klimov show that each slot is defined by a floor, a raised wall and a open end to receive the samples. Answer 5. For convenience, Klimov Figure 1A is reproduced below:



Klimov Figure 1A depicts a front view of a compartment containing test strips, without a cover panel.

Klimov Figure 1B of is also reproduced below:



Klimov Figure 1B depicts a side view of the test strip compartment shown in Figure 1A.

In response to Appellant's argument, the Examiner further notes that Klimov (col. 10, ll. 24-27) discloses that a suitable plastic holder is described in US 5,403,551 (incorporated by reference in Klimov). The Examiner maintains that the '551 patent discloses longitudinal ribs 78 which read on Appellant's raised walls. (Answer 5). In particular, the Examiner references column 5, lines 5+ of the '551 patent which state:

A plurality of spaced apart longitudinal ribs 78 may be disposed on the bars before positioning of the strips 46 and maintaining separation therebetween.

Figure 4 of the '551 patent is reproduced below:

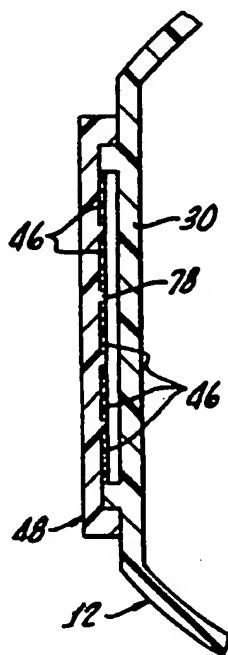


Figure 4 of the '551 patent is a cross-sectional view of plastic holder showing the ribs 78 for maintaining separation between test strips 46.

(2) strips extending beyond the housing

The Examiner maintains that the claim limitation of strips extending beyond the housing is met by Klimov's sample pad 109 which extends beyond the cover 115 to the upper portion of the sample cup. Answer, 6.

(3) a cover for the extended strips which provides a sample port and reservoir for sample analysis

The Examiner found that cover panel 115 reads on Appellant's claimed cover. (Answer 6). The Examiner references column 10, lines 39-

41 for a teaching of the claimed sample ports and column 5, line 64 – col. 6, line 4 for a teaching of the fluid reservoir. (Answer 5).

In his Reply Brief, Appellant argues that the Examiner has improperly tried to combine the cover 115 shown in Fig. 1C with the sample pad 109 and holder 102 shown in Figure 1B. (Reply Br. 5, ll. 8-9). According to Appellant, “Figure 1C, classified as prior art, . . . does not show the sample pad (109) whereas Figure 1B showing the sample pad (109) does not contain the cover element (115) of Figure 1C.” (Reply Br. 5, ll. 10-12). This argument is simply incorrect. *See In re Fritch*, 972 F.2d 1260, 1264-65, 23 USPQ2d 1780, 1782-83 (Fed. Cir. 1992)(a reference stands for all of the specific teachings thereof as well as the inferences one of ordinary skill in this art would have reasonably been expected to draw therefrom). *See also, Hewlett-Packard Co. v. Mustek Sys., Inc.*, 340 F.3d 1314, 1324 n. 6, 67 USPQ2d 1825, 1832 n.6 (Fed.Cir.2003) (“The anticipation analysis asks solely whether the prior art reference discloses and enables the claimed invention, and not how the prior art characterizes that disclosure or whether alternatives are also disclosed”.).

It is clear from the specification that Figs. 1A-1D do not represent separate devices, but depict various parts of Klimov’s apparatus. (See col. 6, ll. 43-47 and col. 10, ll. 21-23 and 53-57).

Appellant further argues that Klimov does not anticipate the claimed invention because the device lacks the feature of a protruding assay dipstick. Thus, Appellant maintains that Klimov’s device is limited to use as a cassette, whereas the device of the invention may be used both as a dipstick and as a cassette. (Reply Br. 5). Appellant’s argument is based on

Klimov Fig. 1B which, according to Appellant, illustrates that the assay strip 104 does not extend beyond the housing, but is enclosed by the wall of the holder 102 and the rubber seal 110.¹ Appellant notes that the only access to sample pad 109 is through a small borehole in holder 102.

Appellant's argument is not persuasive because it is directed to features which are not recited in the claims. *See In re Spada*, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed.Cir.1990)(A reference is anticipatory within the meaning of Section 102 if it discloses each and every claim limitation.). Contrary to Appellant's assertion, the claims do not require that the assay strips extend beyond both the base and cover. Rather, the claims require that the cover have first and second sections, the second section "enclosing the protruding ends of the test strips" and comprising "a sample port formed through which fluid analyte sample may be applied to the protruding ends of the test strips." (Claim 10). Appellant argues that Klimov's cap is solid, i.e., it does not have a sample port. (Reply Br. 5). However, this argument fails to address the Examiner's finding that "the claimed sample port [reads on] the taught sample pads (109) through holes on the back side." (Answer 5). Moreover, Appellant has not directed us to any language requiring that the claimed device be capable of use both as a dipstick and as a cassette.

The Examiner's decision is affirmed.

¹ Appellant also asserts that the assay strip 46 in the '551 patent is totally enclosed by the sample holder 30 and backing plate 48. (Reply Br. 5, ll. 17-19).

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No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a)(1)(iv) (2005).

AFFIRMED

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Bernd W. Sandt
900 Deerfield Sourt
Midland, MI 48640